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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,299	10/27/2003	Peter M. Breining	021663-000110US	4186

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EXAMINER

MANAHAN, TODD E

ART UNIT PAPER NUMBER

3732

DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/695,299

Applicant(s)

BREINING ET AL.

Examiner

Todd E. Manahan

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement filed 07 May 2004 fails to comply with 37 CFR 1.97(c) because it lacks a statement as specified in 37 CFR 1.97(e) or the fee set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered.

### ***Response to Amendment***

The affidavit under 37 CFR 1.132 filed 23 August 2003 is insufficient to overcome the rejection of the claims based upon obviousness over Nicozisis et al. as set forth in the last Office action because:

Applicant has not shown that the results are "unexpected". Any difference between the claimed invention and the prior art may be expected to result in some difference in properties. Applicant's study does not show that use of relaxin provided results that were to such an extent that the difference is unexpected, just that there was an improvement over not using relaxin. Based on Nicozisis et al. such improvement would have been expected by one skilled in the art. Applicant must show that the results were greater than those which would have been expected. *Ex parte The NutraSweet Co.*, 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991).

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Art Unit: 3732

Claim 78 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 78 is directed to a naturally occurring article, a relaxin composition. It has been held that a thing occurring in nature, which is substantially unaltered, is not a "manufacture." A shrimp with the head and digestive tract removed is an example. *Ex parte Grayson*, 51 USPQ 413 (Bd. App. 1941). Statements of intended use, i.e. "for use in the manufacture...." do not alter the article, relaxin composition, in any way.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 78 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nicozisis et al. (Reference 15 on PTO-1449).

Nicozisis et al. disclose a relaxin composition or an analog or mimic thereof. Statements of intended use, i.e. "for use in the manufacture...." Do not carry any patentable weight.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3732

Claims 1-8, 10-19, 22-29, 31-40, 56-64, 66-75, 79-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicozisis et al.

Nicozisis et al disclose use of Relaxin to affect the dentofacial sutural tissues in mice. On page 198, second and third paragraphs, "If mechanical manipulation of the sutures or periodontal ligament is an objective....Perhaps better demonstrative strains could be employed to show the effects of relaxin on the connective tissue of the craniofacial complex and the periodontium...relaxin's effect on the rate of tooth movement may be investigated along with the tendency for relapse once a tooth is moved or rotated." And on page 199, fifth paragraph, "There appears to be a potential application for relaxin as an adjunct to orthodontic therapy. Relaxin affects the collagen types synthesized within the craniofacial sutures and periodontium... It would also be beneficial to examine relaxin's effects on the network of elastin fibers that make up a small, yet important, portion of the gingival proteins." Also on page 199, sixth paragraph, Nicozisis et al disclose some possible applications of relaxin to include "enhancement of tooth movement and stability through reorganization of the PDL fibers" and "enhanced gingival remodeling following space closure". Therefore, based on the suggestion provided by Nicozisis et al, it would have been obvious to one skilled in the art at the time the invention was made to administer relaxin during orthodontic treatment. It is understood that orthodontic treatment involves applying a force to at least one tooth in order to move and/or rotate it into proper position. Regarding claims 8, 10, 11, et al. use of removable appliances, such as aligners, retainers and positioners, or wire and bracket appliances, in order to apply a force to a tooth and effect movement thereof is old and well known in the orthodontic field.

Art Unit: 3732

Claims 9, 30, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicozisis et al. as applied to claims 8, 29, and 64 above, and further in view of Kuo et al. (United States Patent No. 6,607,382).

Kuo et al. discloses a removable orthodontic appliance that includes a reservoir for administering a therapeutic substance concurrently with movement of the teeth. It would have been obvious to use a removable orthodontic appliance that includes a reservoir as taught by Kuo et al. with the method of repositioning teeth and applying relaxin suggested by Nicozisis et al. in order to apply the relaxin concurrently with tooth repositioning.

Claims 20, 21, 41, 42, 76, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicozisis et al. as applied to claims 1, 22, and 56 above, and further in view of Korostoff et al. (United States Patent No. 4,153,060 cited by applicant).

Korostoff et al. disclose applying an electric current to the periodontal tissue to enhance bone growth and tooth movement. It would have been obvious to apply an electric current to the periodontal tissue as taught by Kuo et al. with the method of repositioning teeth and applying relaxin suggested by Nicozisis et al. in order to further enhance bone growth and tooth movement.

Claims 43-46, 48, 51-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo et al. in view of Nicozisis et al.

It would have been obvious to one skilled in the art to use relaxin as the therapeutic agent with the device of Kuo et al. in order to enhance tooth movement and stability as suggested by Nicozisis et al.

Art Unit: 3732

Claims 43-47, 49, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgio (United States Patent No. 6,322,360) in view of Nicozisis et al.

It would have been obvious to one skilled in the art to use relaxin as the therapeutic agent with the device of Burgio in order to enhance tooth movement and stability as suggested by Nicozisis et al.

### ***Response to Arguments***

Applicant's arguments filed 23 August 2004 have been fully considered but they are not persuasive.

In response to applicant's arguments that claim 78 is not directed to a naturally occurring article because it recites a relaxin "composition", it is noted that naturally occurring relaxin is a "relaxin composition".

In response to applicant's argument's that Nicozisis et al. does not anticipate claim 78, on page 192, lines 13 and 14 of the abstract, Nicozisis et al. disclose relaxin in concentrations of 250 and 500 ng/mg, which clearly indicates a relaxin "composition". It is also to be understood that pure relaxin would constitute a "relaxin composition" in the broadest interpretation thereof.

In response to applicant's arguments that the Examiner has not established a *prima facie* case of obviousness, because there is no reasonable expectation of success to administer relaxin during orthodontic treatment, throughout the Discussion beginning on page 196, Nicozisis et al. recite that the effects of relaxin is not limited to the craniofacial structure, but also to the periodontium and thus would have applications in the field of orthodontics. Based upon this results of this study, one would expect success in using relaxin in orthodontology wherein a force is used to move the teeth.

Art Unit: 3732

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

***Conclusion***

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

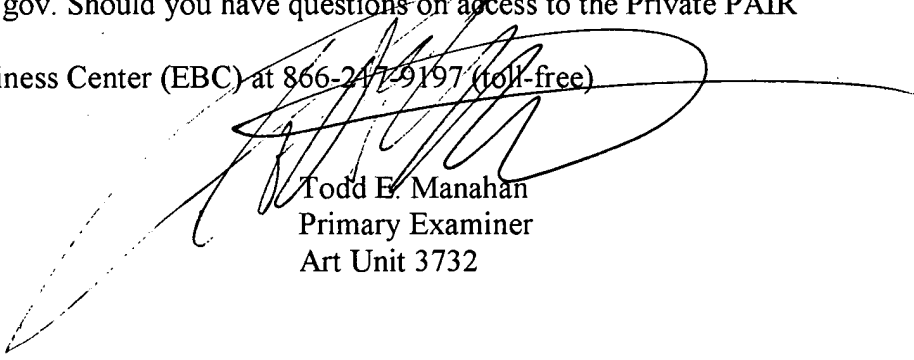
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd E. Manahan whose telephone number is 571 272- 4713. The examiner can normally be reached on Mon-Fri.



Art Unit: 3732

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on 571 273-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-247-9197 (toll-free)



Todd E. Manahan  
Primary Examiner  
Art Unit 3732

T.E. Manahan  
15 November 2004